Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0210590	08/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gtr Washington Medicenter Llc T/A Healthcare Of Gr	6357 Oxon Hill Road, Oxon Hill, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 9/12/2017 for not treating proficiency testing samples in the same manner as patient specimens. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record and patient sample log review and interview with the technical consultant (TC), the laboratory did not handle hematology PT specimens in the same manner as patient samples. Findings: 1. All patient samples which enter the laboratory are recorded on a patient log. 2. A review of patient logs from October, 2018 to June, 2019 showed that hematology PT samples were not documented on the patient log along with patient specimens in 2 of 3 PT events. 3. During an interview on 8/6/19 at 2:00 PM, the TC confirmed that hematology PT samples were not listed individually on the patient log in the same manner as patient specimens.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination,

	and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 9/12/2017 for not maintaining copies of proficiency testing records. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that a copy of all PT documents were maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of 6 PT events from 2017 to 2019 showed that the signed attestation statement, attesting that PT specimens were run in the same manner as patient specimens was not available at the time of the survey for the 3rd PT event of 2018 in hematology; and 2. The hematology instrument printouts from this same PT event were also not available for review at the time of the survey. 3. During an interview on 8/6/19 at 2:00 PM, the TC confirmed that the laboratory did not maintain all PT documents for a minimum of two years from the date of the PT testing event.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not follow written procedures for evaluating new lot numbers of hematology QC before use. Findings: 1. The procedure, "Procedure for Evaluating New Incoming Lots of Hematology Controls" in the SOPM states, "All new incoming lots of hematology quality control materials must be evaluated for 5 days prior to actual use." During an interview at 10:45 AM, the testing person stated that they run the new lot of hematology QC "3 times" before using. 2. A review of hematology QC from September, 2018 to June, 2019 showed that CDS Boule Con Diff Tri-Level hematology controls, lot # 21811-2K, expiration date 3/22/19 was run 1 time before being put in to use; lot # 21902-3K, expiration date 6/24/19 was run 4 times before being put in to use; and lot # 21905-2K, expiration date unknown was run 1 time before being put into use. 3. During an interview on 8/6/19 at 2:00 PM, the TC confirmed that testing personnel did not follow the laboratory's written procedure for evaluating new lot numbers of hematology controls before use. B. Based on standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not follow written

	procedures for documenting problems in quality as they occurred. Findings: 1. The procedure, "Problem Logging" in the SOPM states, "All quality control problems shall be logged, in the appropriate quality control log. If the problem was immediately corrected, for example, by reconstituting new control and rerunning the control, that shall be noted as well." 2. During an interview at 12:45 PM, the TC stated that testing personnel are supposed to document problems with QC and service calls on the problem log. The TC stated that "if QC comes in after 1 rerun, it doesn't have to be written down." 3. A review of hematology QC records from September, 2018 to June, 2019 showed that on 3/25/19 the "Level L" hematology control was out of range. A note on the "Monthly QC L-J Diagram Report" by the TC dated 4/9/19 states, "expired level, new lot paralleled and in use"; and 4. On 4 out of 4 days from 6/14/19 through 6/19/19 the "Level L" hematology control was out of range. A note on the "Monthly QC Control Summary Report" by the TC dated 7/9/19 states, "reagents depleted & QC @ end of stability period. Level 2, 3 were OK so could run. New lot put into use before several parallel testing." 5. A review of the laboratory's "Problem Log Book" showed that the last entry was dated 9/15/16 and that no other problems had been documented since that date. 6. During an interview on 8/6/19 at 2:00 PM, the TC confirmed that testing personnel did not follow the laboratory's written procedure for documenting problems with QC.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant (TC), the laboratory did not ensure that hematology controls were labeled with the date that they were put in to use. Findings: 1. During a tour of the laboratory at 10:15 AM, it was observed that the opened and in use CDS Boule Con Diff Tri-Level hematology controls in the laboratory refrigerator were not labeled with the date that they were put in to use or with the expiration date. 2. During an interview on 8/6/19 at 2:00 PM, the TC confirmed that the hematology controls in use were not labeled with the date that they were opened or with the expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A. Based on quality control (QC) record review and interview with the technical consultant (TC), the laboratory failed to ensure that the lot numbers and expiration dates of reagents and control materials for hematology testing were documented. Findings: 1. The laboratory performs hematology testing on a CDS Medonic M-series

	hematology analyzer. 2. Record review showed that the laboratory had no written documentation of lot numbers and expiration dates of reagents used on the hematology analyzer. A check of the instrument showed that reagent logs were only available through March, 2018. 3. A review of "CDS Boule Con Diff Tri-Level" hematology QC sheets from September, 2018 to June, 2019 showed that the QC sheet from lot # 21905-2K, which included documentation of the expiration date, was not available at the time of the survey. 4. During an interview on 8/6/19 at 2:00 PM, the TC confirmed that documentation of lot numbers and expiration dates of reagents and QC material used for hematology testing were incomplete. B. Based on observation and interview with the testing person and technical consultant (TC), the laboratory failed to ensure that coagulation and chemistry quality control (QC) materials were not used after they had exceeded their expiration date. Findings: 1. During a tour of the laboratory at 10:15 AM, it was observed that the open date written on "Level 1" and "Level 2" QC for the Coag Check XS Plus coagulation instrument was "6/26." No time of reconstitution or expiration date was documented on the vials. 2. Review of the manufacturer instructions showed that each vial of QC is stable for 30 minutes once reconstituted and that the date and time of reconstitution must be written on the vial. During an interview, the testing person stated that they "get at least 2 uses out of a vial"; and 3. It was observed that there was no open or expiration date written on reconstituted vials of "Hemoglobin A1c Normal" and "Abnormal" QC for the Siemens DCA Vantage Analyzer used for hemoglobin A1c testing. Review of manufacturer instructions showed that the QC is stable for 3 months after reconstitution. 4. The box of controls, lot # 0140, expiration date 4/30/21 was labeled with an open date of 5/1 /19. During an interview at 10:30 AM, the testing person stated that the unlabeled vials of QC were probably reconstituted the same day that the box was opened. 5. A second box of QC, lot # 0131, expiration date 1/31/20 contained two QC vials with a reconstitution date of 1/15/19. 6. During an interview on 8/6/19 at 2:00 PM, the TC confirmed that coagulation and chemistry QC was used after it had exceeded its date of expiration.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on competency assessment record review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the policies for monitoring the laboratory staff included the evaluation of the TC. Findings: 1. The laboratory's competency and evaluation records for 2018 and 2019 were reviewed. The documentation did not include an evaluation of the TC. 2. During an interview on 8/6/19 at 2:00 PM, the TC confirmed that an annual competency assessment for the TC was not available for 2018 or 2019.